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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,541	12/28/2004	Tokifumi Majima	MAJIMA I	2562
1444	7590	10/06/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			SINGH, SATYENDRA K	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,541

Applicant(s)

MAJIMA ET AL.

Examiner

Satyendra K. Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-8 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/6/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed with the office on July 12th 2006 is duly acknowledged.

Claims 3, 4, and 9-15 (groups II-IV) are withdrawn from further consideration.

Claims 1, 2 and 5-8 (elected invention of group I) are examined on their merits in this office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. JP 2002-190674, filed on June 28th 2002.

Election/Restrictions

Applicant's election with traverse of group I (claims 1, 2 and 5-8) in the reply filed on July 12th 2006 is acknowledged. The traversal is on the ground(s) that "applicants do not see that Amaike or any other prior art discloses or makes obvious the subject matter of claim 1" and that "there is no lack of unity of invention" (see applicant's remarks, page 2, in particular). This is not found persuasive because the prior art (Amaike et al, [U]) cited by the examiner discloses a composition such as chitosan/acidic biopolymers hybrid fibers in which the inner part comprises chitosan or salts thereof, and is covered with a complex of chitosan and a biodegradable acidic biopolymer (such as gellan gum, which is composed of glucose, rhamnose and glucuronic acid; see Amaike et al, page 287, introduction, and page 288, left column, in particular), thus the invention as claimed lacks unity of invention as the special technical

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feature (i.e. the chitosan/acidic biopolymer hybrid fibers) is known and fully disclosed in the art.

The requirement (as set forth by the examiner in the previous office action) is still deemed proper and is therefore made FINAL.

Claims

Claim 2 has following informalities: The claimed limitation "**hyaluronic acid**" is misspelled, as recited in line 3 of the instant claim. Appropriate correction is required.

Claim Objections

Claims 2, 5-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for ***failing to further limit*** the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites "**A** chitosan/acidic biopolymers hybrid fibers of claim 1....", which is improper and fails to further limit the subject matter of the previous claim 1. Likewise, claims 5-8 recite "Three dimensional scaffolds....." which is improper and fails to further limit the subject matter of the broader claim 1. Applicant is advised to submit amended claims (for example claims reciting "**The** chitosan/acidic biopolymers hybrid fibers") or "The Three dimensional scaffolds" that properly limit the scope of the subject matter being claimed in the instant invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim recites the limitation of “**hybrid fibers**” in the composition (comprising chitosan and acidic biopolymers) claimed, which is confusing. It is unclear as to what is actually encompassed or understood by an artisan of ordinary skill in the art by using the term “hybrid” in the claimed invention. To an artisan of ordinary skill in the art, the term hybrid means “something **heterogeneous** in origin or composition: a composite; or something that has **two different types of components** performing essentially the same function” (see prior art [V], Merriam-Webster Online Dictionary, page 1, in particular). Since, the invention as claimed is directed to a composition (i.e. a fiber) comprising “chitosan/**acidic biopolymers**”, and since the term “hybrid” is not explicitly defined by the applicants in the instant disclosure, it is unclear as to how many biopolymers are in the “hybrid fibers” as claimed in the instant invention of claim 1. Appropriate explanation/correction is required.

Since, claims 2 and 5-8 depend (directly or indirectly) from the broader claim 1, they are also rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim recites the limitation of fibers covered by a complex of chitosan and a biodegradable acidic biopolymers and which retains “the **form**

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thereof....", which is confusing. It is not clear as to what exactly is encompassed and understood by the term "form" as the term "form" is interpreted by an artisan of ordinary skill in the art as meaning (among several other meanings) "the shape and structure of something as distinguished from its material; or a body, as of a person, especially in its external appearance or as distinguished from the face; or a supporting frame model of the human figure or part of the human figure used for display; or one of the different modes of existence, action or manifestation of a particular thing or substance" (see prior art [V], pages 2-3, in particular). Since, the instant disclosure fails to provide an explicit definition of the term "form" used in the invention as claimed, it is unclear as to what shape or structural features of the claimed "hybrid fibers" are being "retained".

Appropriate explanation/correction is required.

Since, claims 2 and 5-8 depend (directly or indirectly) from the broader claim 1, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1. Claims 1 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Amaike et al [U].

Claims are generally directed to a **fiber** composition comprising **chitosan** as the inner part of the fiber, which is **covered** by a biodegradable **acidic biopolymer** (that can form complex with the chitosan polymer, and that the resulting fiber **retains the form** thereof when soaked in DMEM medium at room temperature for 2 weeks); and wherein the fibers of claim 1 are used in the form of **three dimensional scaffolds** (presumably suitable) for **animal cells** (i.e. as a substrate for animal cell adhesion and animal cell culture, or *in vivo* applications; intended use limitation).

Amaike et al [U] teach a fiber composition comprising chitosan as the inner part of the fiber, which is covered by a biodegradable acidic biopolymer (gellan gum, a acidic biodegradable polymeric material, which is composed of glucose, rhamnose and glucuronic acid that can form polyionic complex with the chitosan polymer; see Amaike et al, introduction, and materials & methods, in particular), and can retain the form thereof (see page 288, left column, in particular), and that can be used as a three dimensional scaffold for *in vivo* biological applications (see Amaike et al, page 289, left column, in particular). Since, the fibers as taught by the invention of Amaike et al can themselves act as a three dimensional scaffold (suitable for *in vivo* use), the invention as claimed is fully anticipated by Amaike et al.

It is noted that the cited prior art (Amaike et al, [U]) does not explicitly teach that their composition (i.e. the hybrid fibers) can be used in the manner such as claimed in the instant claims 5-8. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the referenced composition of Amaike et al (see discussion, supra). In order to be limiting, the intended use must create a structural difference between the claimed

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composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the examiner may make rejections under both 35 U.S.C. 102 and 103(MPEP 2112).

2. Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tadashi et al (EP 0544,259 A1; IDS).

Claims are generally directed to a **fiber** composition comprising **chitosan** as the inner part of the fiber, which is **covered** by a biodegradable **acidic biopolymer** (such as hyaluronic acid, or alginic acid, etc. as specifically recited in claim 2; that can form complex with the chitosan polymer, and that the resulting fiber **retains the form** thereof when soaked in DMEM medium at room temperature for 2 weeks); and wherein the fibers of claim 1 are used in the form of **three dimensional scaffolds** (presumably suitable) for **animal cells** (i.e. as a substrate for animal cell adhesion and animal cell culture or *in vivo* applications; intended use limitation).

Tadashi et al (IDS) teach a fiber composition (see abstract; page 2, last paragraph; page 3, lines 39-45; page 7, lines 44-49; examples 10-11; and claims 11-12 and 18-19, in particular) comprising chitosan as the inner part of the fiber, which is covered by a biodegradable acidic biopolymer (such as hyaluronic acid; that can form complex with the chitosan polymer, and that the resulting fiber retains the form thereof when soaked in water for a month; see example 11 and 12, in particular); and wherein the fibers and sheet (or any suitable shape or scaffold structure; see pages 6-7, in particular) made of polyion complex are suitable for use in the form of three dimensional scaffolds for *in vivo* applications; see abstract, and page 8, first paragraph, in particular).

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With regards to the claimed limitations of instant claims 5-8, as discussed supra, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the referenced composition of Tadashi et al (see discussion, supra). In order to be limiting, the intended use must create a structural difference between the claimed composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the examiner may make rejections under both 35 U.S.C. 102 and 103(MPEP 2112).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amaike et al [U] in view of Tadashi et al (EP 0,544 259 A1; IDS).

Claims are generally directed to a **fiber composition** comprising **chitosan** as the inner part of the fiber, which is covered by a biodegradable acidic biopolymer (such as **hyaluronic acid**, or alginic acid, etc. as specifically recited in **claim 2**; that can form complex with the chitosan polymer, and that the resulting fiber retains the form thereof when soaked in DMEM medium at room temperature for 2 weeks); and wherein the fibers of claim 1 are used in the form of three dimensional scaffolds for animal cells (i.e. presumably suitable as a substrate for animal cell adhesion and animal cell culture, or *in vivo* applications).

The teachings of Amaike et al [U] have been discussed above and are further relied upon in the same manner, herein. Amaike et al teach stable and strong fibers comprising chitosan and an acidic biopolymer (such as gellan gum), wherein the inner part of the fiber is made from chitosan and is coated/covered with the acidic biopolymer on the outside using the polysaccharide/polyion complex formation, that retain the form thereof (see discussion, *supra*).

However, a fiber made from chitosan and acidic biopolymer (as recited in the instant claim 1), wherein the acidic biopolymer is selected from the group consisting of **hyaluronic acid**, alginic acid....(see instant claim 2 for specific recitation), is not explicitly taught by the referenced invention of Amaike et al.

As discussed, *supra*, Tadashi et al (EP 0544,259 A1; IDS) teach a fiber composition (see abstract; page 2, last paragraph; page 3, lines 39-45; page 7, lines 44-49; examples 10-11; and claims 11-12 and 18-19, in particular) comprising chitosan as

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the inner part of the fiber, which is covered/coated by a biodegradable acidic biopolymer (such as hyaluronic acid; that can form complex with the chitosan polymer, and that the resulting fiber retains the form thereof when soaked in water for a month; see example 11 and 12, in particular); and wherein the fibers and sheet (or any suitable shape or scaffold structure; see pages 6-7, in particular) made of polyion complex are suitable for use in the form of three dimensional scaffolds for *in vivo* applications; see abstract, and page 8, first paragraph, in particular).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to substitute a functionally analogous acidic biopolymer (such as, a gellan gum) in the invention (i.e. the fiber composition) of Amaike et al with another acidic biopolymer (such as, hyaluronic acid) as explicitly taught by the invention of Tadashi et al (IDS).

One of ordinary skill in the art would have been motivated at the time of invention to make the substitution in the acidic biopolymer (i.e. to use hyaluronic acid in place of gellan gum as an outer covering/coating) in order to obtain excellent biocompatible fibers that have superior stability and tensile strength (see Tadashi et al, page 2, lines 25-27, in particular) as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain

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meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP, "The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945)" (see MPEP 2144.07).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Pertinent prior art not relied upon in the rejections

1. Ohkawa et al. "Self-assembling capsule and fiber formation of polyion complexes of chitosan and poly(α , L-glutamic acid)", *Macromolecular Rapid Communications*, 2000, 21(5): 223-225, especially pages 223-224, and references therein.
2. Vacanti et al. "Guided development and support of hydrogel-cell compositions", US Patent 6,027,744, especially abstract and summary of the invention.
3. Martin et al. "Implantable fibers and medical articles", US Patent 6,162,537, especially abstract, and summary of the invention, and claims.
4. Denuziere et al. "Chitosan-chondroitin sulfate and chitosan-hyaluronate polyelectrolyte complexes: biological properties", *Biomaterials*, 1998, 19: 1275-1285, especially abstract, introduction, in particular.

Conclusion

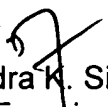
NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

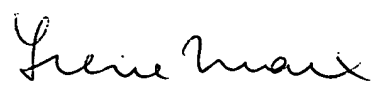
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Satyendra K. Singh
Patent Examiner
Art Unit 1651



IRENE MARX
PRIMARY EXAMINER